ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

GALDERMA LABORATORIES, L.P. and GALDERMA S.A.,	§	
Plaintiffs,	§	4-06CV-471-Y
v.	§	**CAUSE NO.** _____
ACTAVIS MID-ATLANTIC, L.L.C.,	§	
Defendant	§	**Jury Trial Requested**

ORIGINAL COMPLAINT

Plaintiffs, GALDERMA LABORATORIES, L.P. ("Galderma L.P.") and GALDERMA S.A. ("Galderma S.A."), file this Original Complaint against Defendant, ACTAVIS MID-ATLANTIC, L.L.C. ("Actavis"), and state:

INTRODUCTION

1. This is a civil action for patent infringement in violation of the United States Patent Act, 35 U.S.C. § 271, et seq.

2. This suit stems from Actavis' filing of an Abbreviated New Drug Application (the "ANDA") with the United States Food and Drug Administration (the "FDA") pursuant to 21 U.S.C. § 355.

PARTIES

3. Galderma L.P. is a Texas limited partnership, with its principal business address at 14501 N. Freeway, Fort Worth, Texas 76177. Galderma L.P. is the beneficial holder of rights to market Clobex (clobetasol propionate) Lotion, 0.05% ("Clobex Lotion") under FDA approval

of New Drug Application No. 021535 (the "FDA Approval"). Galderma L.P. has an exclusive license from Galderma S.A. to distribute Clobex in the United States.

4. Galderma S.A. is a Swiss corporation, with its principal business address at World Trade Center, Avenue de Gratta-Paille, Case postale 453, CH-Lausanne 30, Switzerland. Galderma S.A. owns United States Patent No. 6,106,848 (the "'848 Patent").

5. Actavis (formerly known as Alpharma USPD, Inc.) is a Delaware limited liability company, with its principal place of business at 200 Elmora Ave., Elizabeth, New Jersey 07207. Actavis may be served with process by and through its registered agent for service of process United Corporation Services, Inc., 874 Walker Road, Suite C, Dover, Delaware 19904.

JURISDICTION AND VENUE

6. This is a complaint for patent infringement and for declaratory judgment of patent infringement. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338(c), as well as 28 U.S.C. §§ 2201 and 2202. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

7. This Court has personal jurisdiction over Actavis in that Actavis sells products for distribution throughout the United States and, on information and belief, regularly conducts business in the State of Texas. Actavis also filed the ANDA for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV Certification") – the acts which give rise to the instant litigation – with knowledge that Galderma L.P. would be injured by such actions in this district, and delivered its Paragraph IV Certification to Galderma L.P. in this district. Moreover, on information and belief, Actavis intends to sell the infringing product in or

for distribution to this district upon approval by the FDA. Actavis has thus purposefully targeted its conduct to cause harm in the State of Texas and this district.

8. Venue is appropriate in this district because the claims asserted herein arise out of an act of patent infringement (i.e. Actavis's filing of the ANDA and issuance of the Paragaph IV certification) purposefully targeting a resident of this district (i.e. Galderma L.P.). Further, because 21 U.S.C. § 355(j)(2)(C)(i)(II) establishes this district as the only venue in which Actavis could file suit seeking a declaration of non-infringement in connection with the ANDA, venue is proper in this district for this action.

BACKGROUND FACTS

A. The '848 Patent

9. On September 22, 1997, Isabelle Preuilh and Nathalie Willcox (inventors) and Centre International de Recherches Dermatologiques (assignee) filed an application with the United States Patent and Trademark Office ("USPTO"), namely, United States Patent Application Serial No. 08/935,054 (the "'054 Application") entitled "Topically Applicable O/W Emulsions Having High Glycol Content and At Least One Biologically Active Agent." On August 22, 2000, based on the '054 Application, the USPTO issued the '848 Patent. A copy of the '848 Patent is attached as Exhibit "A."

10. The '848 Patent is directed to certain emulsions, which are described generally as:

> Stable, topically applicable oil-in-water bioaffecting emulsions having intermediate viscosity, characteristically ranging from 3 to 10 Pa·s, comprise (a) from 30% to 50% by weight of at least one pro-penetrating glycol, (b) at least one emulsifying agent, advantageously an anionic amphiphilic polymer, and (c) at least one biologically active agent, for example an active agent that modulates skin differentiation and/or proliferation and/or pigmentation, an anti-inflammatory, an antibacterial, an antifungal, etc.

'848 Patent at Abstract, p. 1.

11. The '848 Patent is valid, enforceable, and has not expired.

12. Isabelle Preuilh and Nathalie Willcox assigned their rights to and interest in the '054 Application and the '848 Patent to Centre International de Recherches Dermatologiques. Centre International de Recherches Dermatologiques assigned the '848 Patent to Galderma S.A.

13. On July 24, 2003, Galderma L.P. obtained the FDA Approval to market Clobex Lotion. The '848 Patent is listed in the FDA's Approved Drug Products list (the "Orange Book") as reading on Clobex Lotion.

14. On August 18, 2003, Galderma S.A. granted Galderma L.P. the exclusive right to distribute Clobex Lotion in the United States.

B. Actavis's Infringement

15. Upon information and belief, Actavis is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

16. On or about March 24, 2006, Actavis filed ANDA No. 78-223 for Clobetasol Propionate Lotion, 0.05% (the "Accused Product"). Pursuant to the ANDA, Actavis seeks permission from the FDA to market and sell the Accused Product in the United States.

17. On or about May 22, 2006, Actavis mailed a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas, and to Galderma S.A. in Switzerland. A copy of the Certification Letter is attached as Exhibit "B". Through the Certification Letter, Actavis first notified Plaintiffs that Actavis had filed the ANDA with the FDA relating to the Accused Product.

18. In the Certification Letter, Actavis contends that "the claims of [the '848 Patent] are invalid and/or will not be infringed by the commercial manufacture, use or sale of the [Accused Product]." Certification Letter at p. 2. Plaintiffs dispute this contention.

19. Plaintiffs are filing this Original Complaint within forty-five (45) days of receipt of the Certification Letter.

COUNT I
(PATENT INFRINGEMENT)

20. Plaintiffs incorporate paragraphs 1 through 19 above by reference as if fully set forth herein.

21. 35 U.S.C. § 271(e)(2)(A) provides:

> It shall be an act of infringement to submit . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [codified at 21 U.S.C. § 355(j)] or described in section [355(b)(2)] of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

22. The '848 Patent is valid, enforceable, and has not expired. Also, the Accused Product falls within the scope of the claims of the '848 Patent. As such, Actavis infringed the '848 Patent by filing the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '848 Patent.

23. As a result of Actavis' infringement, Plaintiffs are entitled to a declaration that (a) the '848 Patent is valid and enforceable, and (b) the Accused Product infringes the '848 Patent if made, used, sold or offered for sale during the term of the '848 Patent.

24. As a result of Actavis' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity with or acting in

concert with Actavis from manufacturing, selling, or offering the Accused Product for sale during the term of the '848 Patent, or from otherwise infringing or inducing the infringement of the '848 Patent.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs hereby pray for the following relief:

(A) A declaration that the '848 Patent is valid and enforceable;

(B) A declaration, pursuant to 35 U.S.C. § 271(e), that Actavis has infringed one or more claims of the '848 Patent by filing the ANDA;

(C) A declaration, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the ANDA is not to be earlier than the expiration date of the '848 Patent;

(D) A permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Actavis and its officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from manufacturing, selling, or offering the Accused Product for sale, or from otherwise infringing or inducing the infringement of the '848 Patent;

(E) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, including enhanced damages, as a result of Actavis' infringement, if there has been any commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Accused Product prior to expiration of the '848 Patent;

(F) An award, pursuant to 35 U.S.C. §§ 271(e)(4) and 285, declaring this case exceptional and granting Plaintiffs their costs and attorneys fees in pursuing this case; and

(G) Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

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